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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,752	10/19/2001	Reinhold Schmieding	P/1493-443	6145
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DICKSTEIN SHAPIRO LLP			NAJARIAN, LENA	
1825 EYE STREET NW				
Washington, DC 20006-5403			ART UNIT	PAPER NUMBER
			3626	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE		DELIVERY MODE	
3 MONTHS	03/09/2007		PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/981,752	SCHMIEDING, REINHOLD
	Examiner Lena Najarian	Art Unit 3626

**- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 04 December 2006.

2a)  This action is FINAL.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-17 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-17 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. \_\_\_\_.  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.  
5)  Notice of Informal Patent Application  
6)  Other: \_\_\_\_.

**DETAILED ACTION**

***Notice to Applicant***

1. This communication is in response to the Request for Continued Examination (RCE) filed 12/4/06. Claims 1-17 are pending. Claims 1, 8, and 14 have been amended.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Filho (6,089,867) in view of Applicant's admitted prior art (admission) given in "Brief Description of the Related Art" section of application.

(A) Referring to claim 1, Filho discloses a method of providing a customer-oriented integrated product and service package for a surgical procedure, comprising (abstract of Filho):

customizing an allograft to be used in a predetermined surgical procedure, the allograft being customized to predetermined specifications and conditions of a patient and of the predetermined surgical procedure undergone by the patient (col. 5, line 51 – col. 6, line 3 of Filho).

Filho does not teach loaning graft specific surgical instrumentation to match the specifications of the allograft and the procedure.

Admission discloses loaning graft specific surgical instrumentation to match the specifications of the allograft and the procedure (p. 1, lines 12-19 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of loaning surgical instrumentation with the motivation of providing the appropriate instruments if the surgeon or medical facility does not already own the necessary instrumentation (p. 1, lines 12-19 of Specification).

(B) Referring to claim 2, Filho does not disclose coordinating delivery of the allograft to a medical facility at which the surgical procedure is to be performed with the delivery of the surgical instrumentation.

Admission discloses coordinating delivery of the allograft to a medical facility at which the surgical procedure is to be performed with the delivery of the surgical instrumentation (p. 1, lines 12-19 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of coordinating delivery with the motivation of the arrival being within the appropriate time window prior to the surgery (p. 1, lines 12-19 of Specification).

(C) Referring to claim 3, Filho discloses wherein the allograft is harvested at a tissue bank (col. 3, lines 46-53 of Filho).

Filho does not disclose that the allograft is delivered directly to the medical facility.

Admission discloses that the allograft is delivered directly to the medical facility (p. 1, lines 12-19 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of delivering the allograft with the motivation of having the allograft within the appropriate time window prior to the surgery (p. 1, lines 12-19 of Specification).

(D) Referring to claim 4, Filho does not disclose training operating personnel in the use of the instruments and skills to perform the surgical procedure.

Admission discloses training operating personnel in the use of the instruments and skills to perform the surgical procedure (page 1, line 19 - page 2, line 1 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of training operating personnel with the motivation of the surgeon being informed if he or she is unfamiliar with the procedure or needs a refresher course (page 1, lines 19-21 of Specification).

4. Claims 5-6 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Filho (6,089,867) in view of admitted prior art (admission), and further in view of Ramshaw et al. (5,791,907).

(A) Referring to claim 5, Filho and Admission do not expressly disclose providing technical support during the procedure.

Ramshaw discloses providing technical support during the procedure (col. 1, lines 12-24 and 49-65 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Ramshaw within Filho and Admission. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

(B) Referring to claim 6, Filho and Admission do not expressly disclose wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments and the performance of the surgical procedure at an operation location during the procedure.

Ramshaw discloses wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments and the performance of the surgical procedure at an operation location during the procedure (col. 1, lines 12-24 and 49-65 and col. 15, lines 13-17 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Ramshaw within Filho and Admission. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user and notify him/her of incorrect choices (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

(C) Referring to claim 14, Filho discloses a method of providing a customer-oriented integrated product and service package for a surgical procedure, comprising (abstract of Filho):

a customized allograft being sized according to specifications and conditions of a patient and of the predetermined surgical procedure (col. 5, line 51 – col. 6, line 3 of Filho).

Filho does not disclose arranging for the delivery of the customized allograft for a predetermined surgical procedure and providing technical support and/or customer support to operating personnel before and/or during the performance of the procedure.

Admission discloses arranging for the delivery of the customized allograft for a predetermined surgical procedure (p. 1, lines 12-16 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of arranging for the delivery of the allograft with the motivation of the allograft arrival being within the appropriate time window prior to the surgery (p. 1, lines 12-16 of Specification).

Filho and Admission do not expressly disclose providing technical support and/or customer support to operating personnel before and/or during the performance of the procedure.

Ramshaw discloses providing technical support and/or customer support to operating personnel before and/or during the performance of the procedure (col. 2, lines 39-56 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Ramshaw within Filho and Admission. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

(D) Referring to claim 15, Filho discloses wherein the allograft is harvested at a tissue bank (col. 3, lines 46-53 of Filho).

Filho does not disclose that the allograft is delivered directly to a medical facility at which the surgical procedure is to be performed.

Admission discloses that the allograft is delivered directly to a medical facility at which the surgical procedure is to be performed (p. 1, lines 12-19 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of delivering the allograft with the motivation of having the allograft within the appropriate time window prior to the surgery (p. 1, lines 12-19 of Specification).

(E) Referring to claim 16, Filho does not disclose prior to the time the surgical procedure is to be performed, providing training to operating personnel in the use of the instruments and skills to perform the surgical procedure.

Admission discloses prior to the time the surgical procedure is to be performed, providing training to operating personnel in the use of the instruments and skills to perform the surgical procedure (page 1, line 19 – page 2, line 1 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of training operating personnel with the motivation of the surgeon being informed if he or she is unfamiliar with the procedure or needs a refresher course (page 1, lines 19-21 of Specification).

(F) Referring to claim 17, Filho and Admission do not expressly disclose wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments in the instrumentation kit and in the performance of the surgical procedure at an operation location during the procedure.

Ramshaw discloses wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments in the instrumentation kit and in the performance of the surgical procedure at an operation location during the procedure (col. 1, lines 12-24 and 49-65 and col. 15, lines 13-17 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Ramshaw within Filho and Admission. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user and notify him/her of incorrect choices (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Filho (6,089,867) in view of admitted prior art (admission), and further in view of AORN

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Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning").

(A) Referring to claim 7, Filho and Admission do not expressly disclose arranging for the return of the surgical instrumentation after performance of the procedure.

AORN discloses arranging for the return of the surgical instrumentation after performance of the procedure (p. 1062-1063 of AORN).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of AORN within Filho and Admission. The motivation for doing so would have been to return the borrowed instruments to the outside party (p. 1062 of AORN).

6. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Filho (6,089,867) in view of admitted prior art (admission), and further in view of Hamada (US 6,425,920 B1).

(A) Referring to claim 8, Filho discloses a method of providing a customer-oriented integrated product and service package for a surgical procedure, comprising (abstract of Filho):

a customized allograft being sized according to specifications and conditions of a patient and of the predetermined surgical procedure (col. 5, line 51 – col. 6, line 3 of Filho).

Filho does not expressly disclose arranging for the delivery of a customized allograft for a predetermined surgical procedure and customizing a surgical

instrumentation kit specifically designed for use with the customized allograft and for performing the predetermined surgical procedure, wherein the customized surgical instrumentation kit is loaned to the customer for the performance of the surgical procedure.

Admission discloses arranging for the delivery of a customized allograft for a predetermined surgical procedure and wherein the customized surgical instrumentation kit is loaned to the customer for the performance of the surgical procedure (p. 1, lines 12-19 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the aforementioned features within Filho with the motivation of having the allograft within the appropriate time window prior to the surgery and providing the appropriate instruments if the surgeon or medical facility does not already own the necessary instrumentation (p. 1, lines 12-19 of Specification).

Hamada discloses customizing a surgical instrumentation kit specifically designed for use with the customized allograft and for performing the predetermined surgical procedure (col. 1, lines 9-20 of Hamada).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Hamada within Filho and Admission. The motivation for doing so would have been so that the implant is compatible with the instrumentation and procedure (col. 1, lines 9-20 of Hamada).

(B) Referring to claim 9, Filho discloses wherein the allograft is harvested at a tissue bank (col. 3, lines 46-53 of Filho).

Filho does not disclose that the allograft is delivered directly to a medical facility at which the surgical procedure is to be performed.

Admission discloses that the allograft is delivered directly to a medical facility at which the surgical procedure is to be performed (p. 1, lines 12-19 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of delivering the allograft with the motivation of having the allograft within the appropriate time window prior to the surgery (p. 1, lines 12-19 of Specification).

(C) Referring to claim 10, Filho does not disclose prior to the time the surgical procedure is to be performed, providing training to operating personnel in the use of the instruments and skills to perform the surgical procedure.

Admission discloses prior to the time the surgical procedure is to be performed, providing training to operating personnel in the use of the instruments and skills to perform the surgical procedure (page 1, line 19 – page 2, line 1 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of training operating personnel with the motivation of the surgeon being informed if he or she is unfamiliar with the procedure or needs a refresher course (page 1, lines 19-21 of Specification).

7. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Filho (6,089,867) in view of admitted prior art (admission), in view of Hamada (US 6,425,920 B1), and further in view of Ramshaw et al. (5,791,907).

(A) Referring to claim 11, Filho, Admission and Hamada do not disclose providing technical support to operating personnel before and/or during the performance of the procedure.

Ramshaw discloses providing technical support to operating personnel before and/or during the performance of the procedure (col. 1, lines 12-24 and 49-65 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Ramshaw within Filho, Admission, and Hamada. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

(B) Referring to claim 12, Filho, Admission and Hamada do not expressly disclose wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments in the instrumentation kit and in the performance of the surgical procedure at an operation location during the procedure.

Ramshaw discloses wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments in the instrumentation kit and in the performance of the surgical procedure at an operation location during the procedure (col. 1, lines 12-24 and 49-65 and col. 15, lines 13-17 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Ramshaw within Filho, Admission and Hamada. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user and notify him/her of incorrect choices (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Filho (6,089,867) in view of admitted prior art (admission), in view of Hamada (US 6,425,920 B1), and further in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning").  
(A) Referring to claim 13, Filho, Admission and Hamada do not expressly disclose arranging for the return of the customized surgical instrumentation kit after performance of the surgical procedure.

AORN discloses arranging for the return of the surgical instrumentation after performance of the procedure (p. 1062-1063 of AORN).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of AORN within Filho, Admission and Hamada. The motivation for doing so would have been to return the borrowed instruments to the outside party (p. 1062 of AORN).

***Response to Arguments***

9. Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection.

### **Conclusion**

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*JN*

In  
2-20-07

*Joseph Thomas*  
JOSEPH THOMAS  
SUPERVISORY PATENT EXAMINER